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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/797,883

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08/05/2008

EXAMINER

BETTON, TIMOTHY E

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

08/05/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/797,883	Applicant(s) GREEN ET AL.	
	Examiner TIMOTHY E. BETTON	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' Remarks filed on 28 April 2008 have been acknowledged and duly made of record.

The essence of applicants argument is drawn to the alleged improper application of the references as disclosed in the 103(a) rejection. Applicant maintains that based on the need to combine three references in obviousness over the claimed invention deems said claimed invention unobvious.

Specifically, the teachings of Stillman are deemed irrelevant to the patentability to the instant method claims. However, Stillman clearly teaches combination formulations with fiber and red seaweed. In the context of the reference, Stillman also clearly teach this combination as any array of drug formulations including dietary supplements. Thus, the implication of use for a certain purpose would be obvious to one of skill.

In view of Hastings, applicants' attention is directed to the disclosure within the Remarks on page 3, 1st full paragraph. Applicants' disclosure holds no patentable weight in view of the inventive objective of the claimed invention. Applicants will agree that this invention is drawn to a dietary supplement which implies that the target population is generally inclusive. Dosages for such medicaments will vary based on a number of factors and based on any number of factors, variable amounts of each in combination may produce the same desired results. The fact of the matter remains, Hastings adequately teaches daily dosing ranges for Irish moss and psyllium.

Further, applicant purports that the Durrani reference does not adequately suggest synergism and/or additive results. The reference more adequately suggests that Irish moss (carrageen) is well known as a bulking agent. One of skill may readily be inclined to recognize

synergism and/or additive effects based on psyllium as being well-established in the art as a bulking agent. Thus, to combine would obviously produce the same effect toward the same end.

In *re* Kerkhoven adequately encompasses the same subject matter based on two separate components taught in the prior art but the idea of combining is apparent and logically flows in reasoning according to the one of skill.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the three references as cited and made of record reasonably suggest obviousness over claimed invention.

Further, in response to applicant's argument that Hastings is directed to a beverage composition, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on

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combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

In response to applicant's argument that the examiner has combined an excessive number of references, reliance on a large number of references in a rejection does not, without more, weigh against the obviousness of the claimed invention. See *In re Gorman*, 933 F.2d 982, 18 USPQ2d 1885 (Fed. Cir. 1991).

Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejection- 35 USC§ 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stillman (USPGPUB 20030064104) and Hastings (USPN 5,567,424) in view of Durrani (USPN 6,159,491).

Stillman et al teach a shelf-stable, ready to use, water-like composition for humans/animals; as an adjunct to fiber-water, and/or safe drinking water, consumed directly, tube feedings, or in the preparation/reconstitution of food(s)/beverage(s). Fortified Fiber-Water is fiber-water, with added delivery systems: Encapsulations/particles, of different size(s), shape(s), material(s), and colors, non-visible, serving one or more functions: improved taste, odor-masking; controlled release applications; bio-availability of actives, avoid hygroscopicity; minimized interactions, improved thermal, oxidative, and shelf-life; decorative. Viscosity changing elements, (with one or more viscosity changing additives, with or without encapsulations, particles) to enhance delivery of active medicants/ingredients of categories: pharmaceuticals, nutraceuticals, dietary supplements, therapeutics, diagnostics, etc. Composition ensures hydration, simultaneously providing soluble fiber (fiber-water), with additives contained within the delivery systems, having the ability to target specific health goals/needs: weight loss, diabetes, cholesterol/heart, gastrointestinal tract disorders/improvement, osteoporosis, cancer, pain, stress, relaxant, stimulant etc. (Abstract).

Instant claim 8 is obvious over the teachings of Stillman et al. which teach in addition to encapsulated, micro-encapsulated, microparticle, digestive and systemic uses, enzymes can also be used in fiber-water formulations containing encapsulated, micro-encapsulated, micro-particled, herbals (extracts and/or the like), vitamins, minerals, and various other diagnostics, therapeutics, dietary supplements, nutraceuticals, pharmaceuticals, and/or the like known to those skilled in the art, because, in combination they provide a number of unique opportunities.

Stillman et al. teach combination formulations of fiber and red seaweed [0383; 0386; 0387; 0393].

Further, Stillman et al. teach fiber or "roughage" is a component of food that remains undigested as it passes through the gastrointestinal system. The vast majority of dietary fiber consists of polysaccharides of plant origin. The most obvious fiber is the cellulosic wall that surrounds plant cells. Many of these cells are actually called "fibers", hence the name "fiber" for this dietary component. However, there are actually two forms of fiber insoluble fiber--the classic cellulosic material, and soluble fiber--water soluble polysaccharides that are not digested by human or carnivore digestive systems. Both types of fiber bind considerable water and, thus, have a softening effect on the stool. However, soluble fiber may, depending on the precise polysaccharides involved, be metabolized or partially metabolized directly by bacteria in the colon. Both types of fibers tend to increase motility within the gastrointestinal tract thus speeding transit time of wastes and lowering the risk of acute and chronic medical problems. Like water, fiber is essential for human health and is not metabolized by humans. The central issue of claimed invention of an expedited and complete gastrointestinal expulsion of the perianal area is obvious due to the teachings of Stillman above.

Still further, Stillman does teach [the] resulting liquid can be used as a stand-alone product or mixed with a given formula before delivering it to the patient as a single unit (paragraph 1169). This makes instant claim 23 and 24, which were originally objected to, obvious in regard to the subject matter of the Stillman reference. Further, instant claim 24 is made obvious by the teachings and methods of Hastings and Durani in the following portion below.

Hastings teaches a beverage composition that supplies fiber, herbs, antioxidants, and enzymes to the human body. This beverage composition can serve as a food supplement to deliver a combination of nutrients to the body to assist in maintaining good health (Abstract).

Hasting teaches daily dosing ranges for irish moss and psyllium, which are encompassed by the daily dosage ranges in instant claims 2-6. Hastings teaches psyllium ranges of 3.4 grams to 11 grams, which is comparable to many fiber supplements such as Mylanta™, Perdiem Fiber™ and FibreSonic™ (column 1, lines 14-67). Instant claims 2-6 are obvious based upon the teachings of Hastings, which teach psyllium dosage ranges of 250 mg to 24 grams. Accordingly, Hastings teaches irish moss daily dosage ranges of 0.1 grams to 0.5 grams (column 8, line 16; patented reference claim 5), which is also 100 mg to 500mg, respectively. Thus, instant claims 2, 4, and 6 are obvious due to Hastings teaching variable ranges within the dosing range embodiments for seaweed (Irish moss).

Durrani et al teach Irish moss (dried seaweed) as a bulk laxative (col. 9, l. 5). Well-established art also says that psyllium is a well-known bulking agent. Thus, one of skill may readily recognize the high probability that in combination psyllium as well as Irish moss (dried seaweed) would act synergistically.

Thus, it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art.” In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072

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(CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960) (Claims directed to a method and material for treating cast iron using a mixture comprising calcium carbide and magnesium oxide were held unpatentable over prior art disclosures that the aforementioned components individually promote the formation of a nodular structure in cast iron.); and *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992) (mixture of two known herbicides held prima facie obvious). But see *In re Geiger*, 815 F.2d 686, 2 USPQ2d 276 (Fed. Cir. 1987) (“Based upon the prior art and the fact that each of the three components of the composition used in the claimed method is conventionally employed in the art for treating cooling water systems, the board held that it would have been prima facie obvious, within the meaning of 35 U.S.C. 103, to employ these components in combination for their known functions and to optimize the amount of each additive. Appellant argues... hindsight reconstruction or at best, obvious to try’ We agree with appellant.”).

Additionally, the dosage range limitations in reference to instant claims 16, 17, 19, 23, and 24 are also made obvious via the *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings well known in the art, that dosages of any pharmaceutical composition must be adjusted and optimized. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.”

One of ordinary skill in the pertinent art at the time of invention would instantly recognize with reasonable expectation of success, the necessity to combine the inventions of Stillman et al, Hastings, and Durrani. Durrani teaches the motivation to combine psyllium or fiber with a dried seaweed composition. One of ordinary skill in the art would at once recognize the advantage of combining together, which would result in a more facilitated expulsion of gastrointestinal content and perianal content due to the bracing and bulking effect of both components.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy E. Betton whose telephone number is (571) 272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shengjun Wang/

Primary Examiner, Art Unit 1617

TEB